Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2003 list were published in the Federal Register in December 2002.

New Approvals

ANADA Number: 200-320

Pioneer Product:	134-314
Trade Name:	Equell™ Paste
Ingredients:	Ivermectin
Sponsor:	Virbac AH, Inc.
Approval Date:	August 9, 2002
Status:	Over-the-counter
Route:	Oral
Species:	Equine
Drug Form:	Paste
Concentration:	1.87%
Indications:	For treatment and control of the parasites or parasitic conditions: Large Strongyles (adults): *Strongylus vulgaris* (and arterial larval stages), *S. edentatus* (and tissue stages), *S. equinus, Triodontophorus spp.* Small Strongyles (adults and fourth-stage larvae): including those resistant to some benzimidazole class compounds: *Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp., Cylicodontophorus spp.* Pinworms (adults and fourth-stage larvae): *Oxyuris equi* Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum* Hairworms (adults): *Trichostrongylus axei* Large-Mouth Stomach Worms (adults): *Habronema muscae* Neck threadworms (microfilariae): *Onchocerca spp.* Bots (oral and gastric stages): *Gastrophilus spp.* Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi* Intestinal Threadworms (adults): *Strongyloides westeri* Summer Sores: caused by *Habronema and Draschia spp.* cutaneous third-stage larvae.

21CFR 520.1192

ANADA Number: 200-346

Pioneer Product:	140-992
Trade Name:	Component® TE-H
Ingredients:	Trenbolone acetate, estradiol
Sponsor:	Ivy Laboratories, Inc.
Approval Date:	September 27, 2002
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle (heifers fed in confinement for slaughter)
Drug Form:	Implant (ear)
Concentration:	7 pellets with each containing 20 milligrams trenbolone acetate and 2 milligrams estradiol
Indications:	For increased rate of weight gain and improved feed efficiency.
Tolerance:	*21CFR 556.240* Estradiol: Residues for estradiol and related esters may not exceed the following increments above the concentration of estradiol naturally present in untreated animals: In the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion in muscle, 480 parts per trillion in fat, 360 parts per trillion in kidney, and 240 parts per trillion in liver. *21CFR 556.739* Trenbolone: A tolerance for total residues in uncooked edible tissues of cattle is not needed.
Withdrawal:	Zero days

21CFR 522.2477

ANADA Number: 200-306

Pioneer Product:	113-232
Trade Name:	Oxytetracycline Injection
Ingredients:	Oxytetracycline base, USP
Sponsor:	Norbrook Laboratories, Inc.
Approval Date:	June 18, 2002
Status:	Over-the-counter
Route:	Intramuscular, intravenous, and subcutaneous in cattle, intramuscular in swine.
Species:	Swine, beef cattle, dairy cattle, calves including pre-ruminating (veal) calves
Drug Form:	Liquid (solution)
Concentration:	200 milligrams per milliliter
Indications:	Cattle: For the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp*. and *Haemophilus spp*.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. Swine: For the treatment of the bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows as aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.
Tolerance:	*21CFR 556.500* Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef cattle, dairy cattle, calves, swine, as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal:	Cattle - 28 days, milk – 96 hours; swine – 28 days

21CFR 522.1660

ANADA Number: 200-291

Pioneer Product:	135-940
Trade Name:	Clinsol®
Ingredients:	Clindamycin hydrochloride
Sponsor:	Delmarva Laboratories, Inc.
Approval Date:	August 26, 2002
Status:	Prescription only
Route:	Oral
Species:	Dogs and cats
Drug Form:	Liquid (solution)
Concentration:	25 milligrams per milliliter
Indications:	For the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below: Dogs: Aerobic bacteria: For the treatment of soft tissue infections (wounds and abscesses) and dental infections and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*. Anaerobic infections: For the treatment of soft tissue infections (deep wounds and abscesses), dental infections and osteomyelitis caused by or associated with susceptible strains of Bacteroides *fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*. Cats: Aerobic bacteria: For the treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Staphylococcus aureus,* S*taphylococcus intermedius* and *Streptococcus spp.* Anaerobic bacteria: For the treatment of soft tissue infections (deep wounds and abscesses), dental infections caused by or associated with susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*.

21CFR 520.447

ANADA Number: 200-316

Pioneer:	120-161
Trade Name:	Clintabs®
Ingredients:	Clindamycin hydrochloride
Sponsor:	Delmarva Laboratories, Inc.
Approval Date:	June 6, 2002
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Tablets
Concentration:	25, 75, and 150 milligrams per tablet
Indications:	For the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below: Aerobic bacteria: Soft tissue infections (wounds and abscesses), dental infections and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*. Anaerobic bacteria: Soft tissue infections (deep wounds and abscesses), dental infections and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis, Bacteroides melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

21CFR 520.446

ANADA Number: 200-298

Pioneer:	120-161
Trade Name:	Clindamycin Hydrochloride Capsules
Ingredients:	Clindamycin hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	June 14, 2002
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Capsules
Concentration:	25, 75, and 150 milligrams per capsule
Indications:	For the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below: Aerobic bacteria: Soft tissue infections (wounds and abscesses), dental infections and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*. Anaerobic bacteria: Soft tissue infections (deep wounds and abscesses), dental infections and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis, Bacteroides melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

21CFR 520.446

ANADA Number: 200-176

Pioneer Product:	111-607
Trade Name:	Prazitech™ Injection
Ingredients:	Praziquantel
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	October 16, 2002
Status:	Prescription only
Route:	Subcutaneous, intramuscular
Species:	Dogs and cats
Drug Form:	Liquid (solution)
Concentration:	56.8 milligrams per milliliter
Indications:	For the removal of the following cestodes: Dogs – *Dipylidium caninum, Taenia pisiformis, Echinococcus granulosus,* and *Echinococcus multilocularis.* Cats – *Taenia taeniaeformis* and *Dipylidium caninum*.

21CFR 522.1870

NADA Number: 141-171

Trade Name:	Purina Sugar Mag Block 1440 BVT Medicated Mineral Block
Ingredients:	Lasalocid
Sponsor:	Purina Mills, Inc.
Approval Date:	August 20, 2002
Status:	Over-the-counter
Route:	Oral
Species:	Pasture cattle (slaughter, stocker, feeder cattle and dairy and beef replacement heifers)
Drug Form:	Medicated feed block
Concentration:	Type A Medicated Article (68 grams lasalocid activity per pound) to make Type C medicated feed (1440 grams per ton).
Indications:	For increased rate of weight gain.
Tolerance:	*21CFR 556.347* Lasalocid: The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 part per million.
Withdrawal:	Zero days
Patent Number:	4,594,354 Expiration date: June 10, 2003
Exclusivity:	3 years

21CFR 558.311

NADA Number: 141-198

Trade Name:	Tylan® / Bio-Cox®
Ingredients:	Tylosin, salinomycin
Sponsor:	Elanco Animal Health, A Division of Eli Lilly and Co.
Approval Date:	September 4, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Chickens (broiler)
Drug Form:	Type A Medicated Articles to make two-way combination Type C medicated feeds.
Concentration:	Tylosin – 10, 40, or 100 grams activity per pound of Type A Medicated Article, Salinomycin – 30 or 60 grams activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain and improved feed efficiency, and as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunette,* and *E. mivati.*
Tolerance:	*21 CFR 556.740* Tylosin: The tolerances for residues are established in edible products of chickens as follows: 0.2 part per million in uncooked fat, muscle, liver, and kidney. Salinomycin – Not established. The ADI for total residues of salinomycin is 0.005 milligram per kilogram of body weight per day.
Withdrawal:	Zero days

21CFR 558.550 & 558.625

NADA Number: 141-206

Trade Name:	Nuflor® 2.3% Concentrate Solution
Ingredients:	Florfenicol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	September 4, 2002
Status:	Prescription only
Route:	Oral
Species:	Swine
Drug Form:	Liquid (solution)
Concentration:	23 milligrams per milliliter
Indications:	For treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis,* and *Streptococcus suis* Type 2.
Tolerance:	*21CFR 556.283* Florfenicol: Swine – Tolerances are established for residues for marker residue, florfenicol amine, in the liver (target tissue) as 2.5 parts per million and 0.2 part per million is muscle.
Withdrawal:	16 days
Exclusivity:	3 years

21CFR 520.955 & 556.283

NADA Number: 141-208

Trade Name:	Advantage® DUO
Ingredients:	Imidacloprid, ivermectin
Sponsor:	Bayer Corp.
Approval Date:	September 27, 2002
Status:	Prescription only
Route:	Topical
Species:	Canine
Drug Form:	Liquid (solution)
Concentration:	100 milligrams imidacloprid and 800 micrograms ivermectin per milliliter
Indications:	For the prevention of heartworm disease caused by *Dirofilaria immitis*. Also is indicated for the treatment of flea infestation (*Ctenocephalides felis)*.
Exclusivity:	3 years

21CFR 524.1140

NADA Number: 141-207

Trade Name:	A180®		
Ingredients:	Danofloxacin mesylate		
Sponsor:	Pfizer, Inc.		
Approval Date:	September 20, 2002		
Status:	Prescription only		
Route:	Subcutaneous		
Species:	Cattle (beef)		
Drug Form:	Liquid (solution)		
Concentration:	180 milligrams per milliliter		
Indications:	For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida.*		
Tolerance:	*21CFR 556.169* Danofloxacin: The tolerance for parent danofloxacin (marker residue) is 0.2 parts per million in liver (target tissue) and muscle.		
Withdrawal:	4 days		
Patent Number:	4,861,779	Expiration date:	August 19, 2006
	5,811,103		December 19, 2016
Exclusivity:	5 years		

21CFR 522.522 & 556.169

Supplemental Approvals

NADA Number: 141-172

This supplemental application provides for use of ractopamine and tylosin single-ingredient Type A Medicated Articles.

Trade Name:	Paylean® / Tylan®
Ingredients:	Ractopamine hydrochloride, tylosin phosphate
Sponsor:	Elanco Animal Health, A Division of Eli Lilly and Co.
Approval Date:	June 19, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Swine (finishing, from 150 to 240 pounds)
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Ractopamine hydrochloride - 9 or 45 grams of ractopamine activity per pound of Type A Medicated Article; Tylosin phosphate – 10, 40, or 100 grams of tylosin activity per pound of Type A Medicated Article
Indications:	For prevention of swine dysentery (vibrionic), increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine.
Tolerance:	*21CFR 556.570* Ractopamine: A marker residue tolerance is established for ractopamine hydrochloride parent in edible tissues of swine at 0.05 part per million in muscle, and 0.15 part per million in liver, the target tissue. *21CFR 556.740* Tylosin: A tolerance of 0.2 parts per million (negligible residue) in uncooked fat, muscle, liver, and kidney in swine.
Withdrawal:	Zero days

21CFR 558.500

ANADA Number: 200-050

This supplemental application provides for use of the addition of a new species, turkeys.

Trade Name:	Neomycin 325 Soluble Powder
Ingredients:	Neomycin sulfate
Sponsor:	Bimeda, Inc.
Approval Date:	July 10, 2002
Status:	Over-the-counter
Route:	Oral
Species:	Turkeys
Drug Form:	Powder (soluble)
Concentration:	20.3 grams of neomycin sulfate per ounce.
Indications:	For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate.
Tolerance:	*21CFR 556.430* Neomycin: Tolerances are established for residues of parent neomycin in uncooked edible tissues of turkeys as follows: 7.2 parts per million in skin with adhering fat, 3.6 parts per million in liver, and 1.2 parts per million in muscle.
Withdrawal:	Zero days

21CFR 520.1484 & 510.600

ANADA Number: 200-154

This supplemental application provides for the use in lactating dairy cattle.

Trade Name:	Pennox 200
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Pennfield Oil Company
Approval Date:	June 13, 2002
Status:	Over-the-counter
Route:	Intramuscular, intravenous, and subcutaneous in cattle
Species:	Cattle (including lactating dairy)
Drug Form:	Liquid (solution)
Concentration:	200 milligrams per milliliter
Indications:	Cattle: For the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp*. and *Haemophilus spp*.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infection and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.
Tolerance:	*21CFR 556.500* Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef cattle, dairy cattle, calves, swine, as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal:	28 days, milk – 96 hours

21CFR 522.1660

NADA Number: 140-929

This supplemental application provides for the addition of a new species, sheep.

Trade Name:	Micotil® 300 Injection
Ingredients:	Tilmicosin phosphate
Sponsor:	Elanco Animal Health, A Division of Eli Lilly and Co.
Approval Date:	September 4, 2002
Status:	Prescription only
Route:	Subcutaneous
Species:	Sheep
Drug Form:	Liquid (solution)
Concentration:	300 milligrams per milliliter
Indications:	For the treatment of ovine respiratory disease (ORD) associated with *Mannheimia (Pasteurella) haemolytica*.
Tolerance:	*21CFR 556.735* Tilmicosin: A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) at 1.2 parts per million and 0.1 part per million in muscle.
Withdrawal:	28 days
Patent Number:	4,820,695 Expiration Date: April 11, 2006

21CFR 522.2471 & 556.735

NADA Number: 039-417

This supplemental application provides for a revised range of concentrations for the use of decoquinate in cattle, sheep and goats.

Trade Name:	Deccox®
Ingredients:	Decoquinate
Sponsor:	Alpharma, Inc.
Approval Date:	September 4, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle, calves (ruminating and non-ruminating including veal), sheep, goats
Drug Form:	Type A Medicated Article to make Type C medicated feed.
Concentration:	27.2 grams activity per pound of Type A Medicated Article.
Indications:	Cattle - For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii.* Sheep - For the prevention of coccidiosis caused by *E. ovinoidalis, E. crandallis, E. parva,* and *E. bakuensis*. Goats - For the prevention of coccidiosis in young goats caused by *E. christenseni,* and *E. ninakohlyakimovae*
Tolerance:	*21CFR 556.170* Decoquinate: Tolerances are established for residues in the uncooked, edible tissues of cattle and goats as follows: 1 part per million in skeletal muscle and 2 parts per million in other tissues.

21CFR 558.195

ANADA Number: 200-008

This supplemental application provides for the use in lactating cattle.

Trade Name:	Bio-Mycin® 200, Oxy-Tet® 200
Ingredients:	Oxytetracycline
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	September 3, 2002
Status:	Over-the-counter
Route:	Intramuscular, subcutaneous, intravenous in cattle; intramuscular in swine
Species:	Cattle (including lactating dairy)
Drug Form:	Liquid (solution)
Concentration:	200 milligrams per milliliter
Indications:	Cattle - For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.
Tolerance:	*21CFR 556.500* Oxytetracycline***:*** Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney. In milk the tolerance is 0.3 part per million.
Withdrawal:	28 days, milk – 96 hours
Patent Number:	5,075,295 Expiration Date: December 12, 2009

21CFR 522.1660

ANADA Number: 200-189

This supplemental application provides for reducing the preslaughter withdrawal time from six to zero days in swine.

Trade Name:	Lincomycin Soluble
Ingredients:	Lincomycin hydrochloride
Sponsor:	Alpharma, Inc.
Approval Date:	September 19, 2002
Status:	Over-the-counter
Route:	Oral
Species:	Swine
Drug Form:	Powder (soluble)
Concentration:	16 grams lincomycin per 40-gram packet
Indications:	For the treatment of swine dysentery (bloody scours).
Tolerance:	*21CFR 556.360* Lincomycin: Tolerances of 0.6 parts per million in liver and 0.1 parts per million in muscles of swine.
Withdrawal:	Zero days

21CFR 520.1263c

ANADA Number: 200-130

This supplemental application provides for use in an additional species, growing turkeys.

Trade Name:	Neo-Sol® 50
Ingredients:	Neomycin sulfate
Sponsor:	Alpharma, Inc.
Approval Date:	October 25, 2002
Status:	Over-the-counter
Route:	Oral
Species:	Turkeys (growing)
Drug Form:	Powder (soluble)
Concentration:	71.5 grams of neomycin sulfate (equivalent to 50 grams neomycin) per packet.
Indications:	For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate.
Tolerance:	*21CFR 556.430* Neomycin: Tolerances are established for residues of parent neomycin in uncooked edible tissues of turkeys as follows: 7.2 parts per million in skin with adhering fat, 3.6 parts per million in liver, and 1.2 parts per million in muscle.
Withdrawal:	Zero days

21CFR 520.1484

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-043

This supplemental application provides for use at an additional dosing level.

Trade Name:	Synovex ® Choice
Ingredients:	Trenbolone acetate, estradiol benzoate
Sponsor:	Fort Dodge Animal Health, Division of Wyeth
Approval Date:	October 3, 2002
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle (steers)
Drug Form:	Implant (ear)
Concentration:	100 mg trenbolone acetate and 14 mg estradiol benzoate per implant
Indications:	For increased rate of weight gain in steers fed in confinement for slaughter.
Tolerance:	*21CFR 556.240* Estradiol and related esters: The tolerance in uncooked edible tissues of heifers, steers, and calves are: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver. *21 CFR 556.739* Trenbolone: A tolerance is not needed. The Acceptable Daily Intake (ADI) for total residues of trenbolone is 0.4 microgram per kilogram of body weight per day.
Withdrawal:	Zero days
Exclusivity:	3 years

21CFR 522.2478

Change of Sponsor

NADA Number: 128-550

From: Boehringer Ingelheim Vetmedica, Inc.
To: Pennfield Oil Co.
14040 Industrial Rd.
Omaha, NE 68137
Drug labeler code: 053389

NADA Numbers:

006-084	008-774	011-582	011-644	013-957
015-160	033-342	033-606	033-653	033-654
033-655	047-033	055-012	055-018	055-020
055-039	065-071	065-269	065-270	065-313
065-440	065-441	122-271	122-272	140-844

From: American Cyanamid, Division of American Home Products
To: Fort Dodge Animal Health, A Division of American Cyanamid Co.
P.O. Box 1339
Fort Dodge, IA 50501
Drug labeler code: 053501

Change of Sponsor Address

Sponsor:	Bimeda, Inc.
From:	288 County Rd. 28 LeSuer, MN 56058-9322
To:	291 Forest Prairie Rd. LeSuer, MN 56058 Drug Labeler Code: 061133
Sponsor:	Phoenix Scientific, Inc.
From:	3915 South 48th St. Terrace P.O. Box 6457 St. Joseph, MO 64506-0457
To:	3915 South 48th St. Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
Sponsor:	Delmarva Laboratories, Inc.
From:	2200 Wadebridge Rd. P.O. Box 525 Midlothian, VA 23113
To:	1500 Huguenot Rd., Suite 106 Midlothian, VA 23113 Drug Labeler Code: 059079

Suitability Petition Action

Number:	02P-0396/CP1
Sponsor:	Intervet, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste 1.87%, Merial Ltd., NADA 134 -314 by the following characteristics: The generic product will consist of a different dosage form ('soft-chew') and strength (0.45%) from the pioneer.
Action:	Approved December 10, 2002.
Number:	02P-0416/CP1
Sponsor:	Highland VetPharma, LLC
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin, which differs from the pioneer product, Eqvalan®, Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form (palatable chewable bolus) and strength (22.75 milligrams per 'chewable') from the pioneer.
Action:	Approved on December 10, 2002.
Number:	02P-0423/CP1
Sponsor:	Highland VetPharma, LLC
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, Heartgard® Plus, Merial Ltd., NADA 140-971 by the following characteristics: the generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).
Action:	Approved on December 10, 2002.

Actions Taken by FDA Center for Veterinary Medicine

Number:	02P-0429/CP1
Sponsor:	Highland VetPharma, LLC
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Heartgard® for Cats, Merial Ltd., NADA 141-078 by the following characteristics: the generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).
Action:	Approved on December 10, 2002.

Number:	02P-0470/CP1
	Sponsor: Karen A. Sisson
	Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan®, Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form (granule/crumble) from the pioneer.
Action:	Filed on October 31, 2002.

Technical Amendment

The Food and Drug Administration (FDA) is amending the animal drug regulations for preslaughter withdrawal time for lincomycin soluble powder products used to make medicated drinking water for swine to correct inadvertent editorial errors. FDA has found that Sec. 520.1263c (21 CFR 520.1263c) does not reflect the approved preslaughter withdrawal time for three lincomycin soluble powder products used to make medicated drinking water for swine. The six-day withdrawal time was inadvertently removed for a generic product approved under ANADA 200-189 at the time it was being removed for the pioneer product approved under NADA 111-636 (64 FR 13341, March 18, 1999). The conditions of use for two other products approved February 4, 1999, under ANADA 200-241 (64 FR 13508, March 19, 1999) and September 22, 1999, under ANADA 200-233 (64 FR 66382, November 26, 1999) were subsequently codified without a withdrawal period. At this time, the regulations are being amended in Sec. 520.1263c to correct these errors. This rule is effective December 3, 2002.